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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,939

03/31/2004

Jimo Borjigin

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9629 7590 07/22/2009  
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EXAMINER

EBRAHIM, NABILA G

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/812,939	<b>Applicant(s)</b> BORJIGIN, JIMO	
	<b>Examiner</b> NABILA G. EBRAHIM	<b>Art Unit</b> 1618	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 05 June 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): 35 USC §112 first and second paragraph of cancelled claim 8.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-7,9-11,15-19 and 24-26.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

/Michael G. Hartley/  
 Supervisory Patent Examiner, Art Unit 1618

/NABILA G EBRAHIM/  
 Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the claimed invention is directed to a method for identifying an agent that modulates a preselected condition controlled by the circadian clock and that Applicants are not required to provide the structure of the agents to be tested. This arguments are not not persuasive because though claim 1 recites a method for identifying at least one agent which modulates a preselected biological condition controlled by the circadian clock in a subject, the claim also recites monitoring the same preselected biological condition in a second subject after contacting the second subject with THE AT LEAST ONE AGENT. Thus, it is clear that the agent is not being identified, the agent is known and its modulating effect is being tested in a preselected condition. Applicant also argues that the agent is defined in the specification as being chemical or metabolite. This was not persuasive because defining a substance as being a chemical is misleading since everything on earth is made of chemical molecules and this definition does not specify any meaning to the word "agent". In addition, Applicant argues that specification further provides guidelines as to suitable boundaries for what the term "agent" encompass in page 13, [0062]: "Agents envisioned to be used in the practice of the invention include pharmacologically active agents, therapeutic agents, biological molecules, amino acids...neuropeptides...mammalian tachykinins..., agonists, antagonists and derivatives of all of the above.", It is clear that Applicant is accurate in calling these chemicals "guidelines" to to the claimed agent because the AGENT is not defined or exemplified. It is noted that a general statement about an agent is not sufficient to test its effect absent a disclosure of what agent is being tested. There is no structure/function relationship to show that applicant envisioned the genus of such an agent defined by function only at the time of filing. There is no reasonable number of species defined showing a structure/function relationship to support the definition by function only, and the term is not a term of art in which one would readily envision the genus described by function only. Applicant argues that Lu's method has no reasonable success expectation because pineal of the bird is removed and that the instant method is less invasive than Ziyal. Applicant alleges that Lu and Ziyal are teaching away from the instant claimed invention. However, Lu and Ziyal are relied upon for teaching the step of opening the skull over the sinuses to expose the pineal and both references disclose that the subject was not sacrificed after the procedure. Regarding the less invasive procedure as argued by Applicant, it is noted that the argument is not persuasive because Ziyal is a secondary reference. Applicant also argues that there is no reason to combine the teachings of Lu and Ziyal with those of Drijhout, Arendt, and Sun and there is no reasonable expectation of success in obtaining the claimed invention by combining all the cited references. The office action is clear regarding the two references stating that " Thus the two references teach the step of opening the skull over the sinuses to expose the pineal and both disclose that the subject was not sacrificed after the procedure." Applicant argues that there is stated in the cited reference of Drijhout, in vivo insertion of a monitoring device into the pineal gland has drawbacks, particularly with respect to the monitoring device damaging the sinuses (see Drijhout at page 937, left column, first paragraph). To respond, it is noted that drawbacks does not mean that it was impossible, any surgery to an organ related to the brain has drawbacks, if Applicant thinks otherwise, Applicant is invited to show any evidence that claims ease in operating on the brain or any anatomically related organ. Finally, Applicant argues that the present invention is directed to a method of accessing the pineal gland, inserting a monitoring device and then monitoring the subject's circadian rhythm. Lu and Ziyal, however, are directed to opening a skull and removing either the entire pineal or a part of the pineal containing tumors, and sewing the subject back up. Accordingly, there is no reason to combine the teachings of Lu and Ziyal with those of Drijhout, Arendt, and Sun and there is no reasonable expectation of success in obtaining the claimed invention by combining all the cited references. To respond to this argument, it is noted that surgical procedures for a specific area are almost the same until surgeon reaches a specific point when the different purpose of the operation controls the procedures. For example to reach any organ in the abdomen a surgeon should open through 1) the skin, 2) superficial fascia 3) deep fascia 4) subserous fascia and 5) the peritoneum. Starting after the peritoneum, the surgeon starts to direct the procedure towards the targeted organ such as the liver, gall bladder, stomach, duodenum .. etc. Thus, the references cited are all related to procedures in the pineal and reaching the pineal body should open through the same anatomical structures regardless of the purpose which may be removing a tumor such as in Ziyal or monitoring the subject's circadian rhythm such as in Drijhout